IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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| GLADYS E. MAJETTE, et al. | * | |
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| v. | * | Civil No. CCB-05-683 |
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| OLYMPUS AMERICA INC. | * | |
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**MEMORANDUM**

Daisy E. Matthews ("Matthews") died from complications allegedly related to a procedure she underwent at Johns Hopkins Hospital ("Johns Hopkins"). The personal representative of Matthews' estate joined with Matthews' surviving spouse and children (collectively, the "Plaintiffs") to file this product liability action against Olympus America Inc. ("OAI"), the supplier and distributor of the medical device used in the aforementioned procedure. Now pending before me is OAI's motion for summary judgment. For the reasons that follow, I will deny OAI's motion.

**BACKGROUND**

Johns Hopkins admitted Matthews on September 28, 2001 for repair of a thoracic aneurysm. (Kaye Decl. ¶¶ 3-4, Ex. 1 to Pls.' Opp'n Mem.) On October 12, 2001, Matthews underwent a bronchoscopy to examine her lungs. (*Id.* ¶ 4.) Just eleven days later, Matthews tested positive for *Pseudomonas aeruginosa*, a pathogen that can cause various infections and is often present throughout a hospital. (*Id.* ¶ 5; Rutala Decl. ¶¶ 4-5, Ex. B to Def.'s Mem.) In fact, around the time of Matthews' hospitalization, Johns Hopkins experienced a *Pseudomonas aeruginosa* outbreak attributed to bronchoscopes. (Kaye Decl. ¶ 7, Ex. 1 to Pls.' Opp'n Mem.) By early November 2001, *Pseudomonas aeruginosa* was detected in Matthews' blood. (*Id.* ¶ 5.)

Despite the institution of antibiotic treatment, the infection worsened and ultimately led to Matthews' death on January 1, 2002. (*Id.* ¶ 6.)

At the time of Matthews' bronchoscopy in October 2001, Johns Hopkins owned thirty-eight bronchoscopes. (Perl Dep. at 72-73, Ex. A to Def.'s Mem.) Because the hospital did not record the serial number of the bronchoscope used on each patient, it is impossible to identify from the medical records the precise device used for Matthews' procedure. (*Id.* at 35-36.) Nevertheless, according to a Johns Hopkins representative, the bronchoscope used on Matthews was one of eight stored in the hospital's endoscopy suite. (*Id.* at 25, 37-38.) Those eight bronchoscopes all were manufactured by Olympus and distributed by OAI. (*Id.* at 32.)

In November 2001, shortly after Matthews' procedure, OAI recalled a number of Olympus bronchoscopes. (Storms-Tyler Aff. ¶ 4.)[1] Of the eight most likely used for Matthews' bronchoscopy, five were recalled. (*Id.* ¶¶ 5-6.) Although their design renders all bronchoscopes difficult to sterilize, certain loose parts on these models in particular harbored bacteria, thereby preventing proper disinfection between procedures. (Rutala Decl. ¶ 10, Ex. B to Def.'s Mem.; Kaye Decl. ¶ 8, Ex. 1 to Pls.' Opp'n Mem.) After OAI initiated the recall, the outbreak at Johns Hopkins subsided. (Arjun Srinivasan, M.D. et al., *An Outbreak of* Pseudomonas aeruginosa *Infections Associated with Flexible Bronchoscopes*, 348 New Eng. J. Med. 221, 226 (2003), Ex. B to Rutala Decl.) *Pseudomonas aeruginosa* strains obtained at the end of the outbreak from three contaminated bronchoscopes did not match Matthews' cultures. (Rutala Decl. ¶ 14, Ex. B to Def.'s Mem.)

[1] OAI submitted this affidavit in response to inquiries made as a result of an October 6, 2006 hearing regarding a motion to compel discovery.

Despite this inability to match the strains of *Pseudomonas aeruginosa*, Plaintiffs maintain that all of the other evidence suggests that Matthews' fatal infection stemmed from her exposure to a bronchoscope which was defective and subsequently recalled. Thus, they have filed the instant action asserting product liability claims against OAI based on strict liability, negligence, breach of implied warranty of merchantability, breach of express warranty, and fraud. (Am. Compl. ¶¶ 17-61.)

The parties have engaged in discovery related to product identification, and OAI now moves for summary judgment. It argues that Plaintiffs' claims fail because they cannot identify the exact bronchoscope used on Matthews in October 2001, let alone that it was later recalled. I find, however, that Plaintiffs have created a genuine issue of material fact as to whether the bronchoscope used for Matthews' procedure was one of those subject to the recall. As a result, I will deny OAI's motion.

**ANALYSIS**

Rule 56(c) of the Federal Rules of Civil Procedure provides that summary judgment:

> shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.

The Supreme Court has clarified that this does not mean that any factual dispute will defeat the motion:

> By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.

*Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original).

"The party opposing a properly supported motion for summary judgment 'may not rest upon the mere allegations or denials of [his] pleadings,' but rather must 'set forth specific facts showing that there is a genuine issue for trial.'" *Bouchat v. Balt. Ravens Football Club, Inc.*, 346 F.3d 514, 525 (4th Cir. 2003) (alteration in original) (quoting Fed. R. Civ. P. 56(e)). The court must "view the evidence in the light most favorable to . . . the nonmovant, and draw all reasonable inferences in her favor without weighing the evidence or assessing the witness' credibility," *Dennis v. Columbia Colleton Med. Ctr., Inc.*, 290 F.3d 639, 644-45 (4th Cir. 2002), but the court also must abide by the "affirmative obligation of the trial judge to prevent factually unsupported claims and defenses from proceeding to trial." *Bouchat*, 346 F.3d at 526 (internal quotation marks omitted) (quoting *Drewitt v. Pratt*, 999 F.2d 774, 778-79 (4th Cir. 1993), and citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)).

A plaintiff asserting product liability claims in Maryland must show: (1) the existence of a defect; (2) the attribution of the defect to the seller; and (3) a causal relation between the defect and the injury. *Giddings v. Bristol-Myers Squibb Co.*, 192 F. Supp. 2d 421, 423 (D. Md. 2002) (citing *Jensen v. Am. Motors Corp.*, 437 A.2d 242, 247 (Md. Ct. Spec. App. 1981)). Issues such as causation may be proven by circumstantial evidence, *see Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 786 (4th Cir. 1998), and a plaintiff need not negate every possible scenario, nor demonstrate the "exact mechanics of injury." *See Bell v. Heitkamp, Inc.*, 728 A.2d 743, 750 (Md. Ct. Spec. App. 1999); *Unsatisfied Claim & Judgment Fund Bd. v. Bowles*, 334 A.2d 532, 535 (Md. Ct. Spec. App. 1975). "A party's evidence is sufficient to reach a jury under federal law when a jury could reasonably embrace that party's theory of the case." *Binakonsky v. Ford*

*Motor Co.*, 133 F.3d 281, 289 (4th Cir. 1998).[2]

Applying these standards to the record developed in this case, I find that Plaintiffs have offered sufficient evidence to show by a preponderance of the evidence that a recalled bronchoscope was used for Matthews' bronchoscopy and that this exposure ultimately led to her death. Of the eight bronchoscopes most likely used for Matthews' procedure, five were later recalled. (Storms-Tyler Aff. ¶ 5.) Plaintiffs' expert, Dr. Keith S. Kaye, considered this circumstance, along with other factors, in opining that a "contaminated bronchoscope was the sole and proximate cause of [Matthews'] infection." (Kaye Decl. ¶ 19, Ex. 1 to Pls.' Opp'n Mem.) As Dr. Kaye explains, the eleven-day period between Matthews' bronchoscopy and her initial positive test for *Pseudomonas aeruginosa* is "medically compatible" with a conclusion that she contracted the infection via the procedure. (*Id.* ¶ 12.)[3] Indeed, even if only one of the eight bronchoscopes had been recalled, Dr. Kaye would conclude on the strength of this temporal relationship that a "tainted" device caused the infection.[4] (*Id.* ¶ 19.) Finally, Johns

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[2] OAI suggests that the product identification analysis does not implicate the element of causation. (Def.'s Mem. at 11 n.2; Def.'s Reply Mem. at 6-7.) To the contrary, these issues are closely intertwined in that if Plaintiffs fail to sufficiently identify the bronchoscope used on Matthews as among those later recalled, there can be no showing that such a device caused her death. It is therefore appropriate, in resolving OAI's pending motion for summary judgment, to rely on cases addressing causation.

[3] The Srinivasan study explained that infections were considered "potentially attributable to bronchoscopy if they occurred in the 14 days after a procedure." (Arjun Srinivasan, M.D. et al., *An Outbreak of* Pseudomonas aeruginosa *Infections Associated with Flexible Bronchoscopes*, 348 New Eng. J. Med. 221, 222-23 (2003), Ex. B to Rutala Decl.)

[4] OAI points out that rather than link Matthews' infection to a "recalled" bronchoscope, Dr. Kaye merely opines that she contracted *Pseudomonas aeruginosa* from a "contaminated" or "tainted" device. (Def.'s Reply Mem. at 3-5.) Because perfectly functioning bronchoscopes may harbor bacteria, OAI argues that "contaminated" and "tainted" are not synonymous with "recalled." (*Id.* at 4.)

Dr. Kaye, however, explains that if five of the eight bronchoscopes potentially used on

Hopkins experienced no other major *Pseudomonas aeruginosa* outbreaks in late 2001 apart from those cases related to the bronchoscopes, and the outbreak ended after OAI recalled the devices. (*Id.* ¶ 20; Arjun Srinivasan, M.D. et al., *An Outbreak of* Pseudomonas aeruginosa *Infections Associated with Flexible Bronchoscopes*, 348 New Eng. J. Med. 221, 224, 226 (2003), Ex. B to Rutala Decl.) Accordingly, a genuine issue of material fact exists as to whether the bronchoscope used on Matthews was among those subsequently recalled.

The authorities upon which OAI relies are distinguishable or indeed support the foregoing conclusion. For example, unlike *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831 (D. Md. 2000) and *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89 (D. Md. 1989), because OAI distributed all of the Olympus bronchoscopes to which Matthews was potentially exposed, there is no question here as to the seller or manufacturer's identity.[5] The opinion in *Giddings v. Bristol-Myers Squibb Co.*, 192 F. Supp. 2d 421 (D. Md. 2002), rested on the lack of qualifications of the plaintiff's expert. Cases dealing with the sufficiency of a person's exposure to products containing asbestos support the Plaintiffs here, as they can show better than a 50% chance of exposure to a recalled bronchoscope. *See Shetterly v. Raymark Indus., Inc.*, 117 F.3d

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Matthews were later recalled, "it is more likely than not, that a tainted bronchoscope was used on [her]." (Kaye Decl. ¶ 11, Ex. 1 to Pls.' Opp'n Mem.) Thus, Dr. Kaye appears to use "recall" and "tainted" interchangeably. While a more explicit opinion would be preferable, I am not prepared to grant OAI's motion for summary judgment on this basis, particularly given that members of Johns Hopkins' staff noted after the outbreak that only those bronchoscopes implicated in the recall were contaminated. (Arjun Srinivasan, M.D. et al., *An Outbreak of* Pseudomonas aeruginosa *Infections Associated with Flexible Bronchoscopes*, 348 New Eng. J. Med. 221, 226 (2003), Ex. B to Rutala Decl.) Such a finding implies that OAI overstates the distinction between these terms.

[5] In neither *Miller* nor *Lee* could the plaintiff show that any one of two or more companies more likely manufactured the breast implant that allegedly caused the plaintiff's injuries.

776, 781 (4th Cir. 1997); *Owens-Corning Fiberglas Corp. v. Garrett*, 682 A.2d 1143, 1156-57 (Md. 1996); *cf. Owens-Illinois, Inc. v. Zenobia*, 602 A.2d 1182, 1185 (Md. 1992). In summary, OAI appears to argue that product identification, unlike other elements of the Plaintiffs' claims, must be shown by direct evidence only, and to a mathematical certainty rather than a reasonable probability. The cases cited do not support this contention.

Further, the fact that Matthews' *Pseudomonas aeruginosa* cultures did not match the strains recovered from three bronchoscopes at the end of the outbreak does not mandate dismissal of Plaintiffs' action at this stage of the proceedings. Plaintiffs' expert states that these results do not affect his opinion that Matthews contracted *Pseudomonas aeruginosa* from a contaminated bronchoscope. (Kaye Decl. ¶ 16, Ex. 1 to Pls.' Opp'n Mem.) Dr. Kaye explains that because a number of strains may have tainted the devices over the course of the outbreak at Johns Hopkins, it is reasonable that the three strains recovered at the end of the outbreak might not match Matthews' cultures. (*Id.* ¶ 17.) In fact, a number of strains from other Johns Hopkins patients also failed to match those recovered from the bronchoscopes. (*Id.* ¶ 18.)

OAI assails Dr. Kaye's "ever changing microorganism" theory as having no basis in reliable scientific methodology. (Def.'s Reply Mem. at 9-10.) But, as OAI acknowledges elsewhere in its briefs, the reliability of Dr. Kaye's opinion has not formally been challenged at this stage of the litigation. (Def.'s Mem. at 11 n.2; Def.'s Reply Mem. at 6 n.2.) As a result, I will not grant OAI's motion for summary judgment on these grounds.

For the foregoing reasons, I find sufficient evidence in the record to raise a genuine issue of material fact as to whether Matthews was exposed to a recalled bronchoscope in October 2001. Therefore, OAI's motion for summary judgment will be denied.

A separate Order follows.

August 8, 2007
Date

/s/
Catherine C. Blake
United States District Judge